

K982150 EL-ANA PROFILES: EL-ENA/4Aug 13, 1998
56 days to decisionK982150 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k982150/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jun 18, 1998
Decision date	Aug 13, 1998
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Theratest Laboratories, Inc.
Location	Chicago, IL, US
Contact	MARIUS TEODORESCU
510(k) history	22 submissions · 22 cleared · 1991-2010

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